REMARKS

The Action states that claims 22-33, 36-65 and 74-87 are pending and stand rejected as final.

Applicants disagree with the status of the claims. In particular, there is no indication of the status of claims 1-3, 5, 6, 8-10, 21, 34, 35 and 66-73, suggesting that they have been canceled. Instead, these claims should be indicated as merely withdrawn from consideration, as per the preceding Office Action.

Before addressing the prior art rejections, Applicants believe that a brief review of the invention would be helpful to its understanding.

The present invention pertains to a prosthetic device containing fibers that are at least partially aligned. Prosthetic devices can be used in the repair, augmentation or replacement of diseased or damaged organs such as muscles (e.g., rotator cuff injuries), intervertebral disc, ligaments, or defects in the *dura mater* or abdominal wall, among other applications. The fibrous prosthetic devices of the present invention are structurally stable, pliable, suturable, and can be made porous or non-porous.

The fibrous prosthetic devices of the present invention may be prepared by providing a slurry containing at least a plurality of biodegradable polymer fibers in a fluid, optionally also containing a lubricant. The slurry is then compressed to expel at least some of the fluid. The compressing typically is performed in a mold which may be shaped to yield a prosthetic article of desired size and shape. A piston typically is used to compress the slurry, and during compression, the mold is not rotated relative to the piston. Something remarkable occurs: the fibers migrate through the remaining fluid and begin to organize themselves into a plurality of layers or plates. The fibers tend to align within a given layer or plate, but the layers or plates themselves are not necessarily aligned with respect to one another, at least not during this early stage of compression. The layers or plates define fluid planes which may exist as multiple fissures located randomly throughout the structure. Additional compression brings the layers or plates of fibers into closer contact, allowing them to become locked into a compact anisotropic structure, although the material may be isotropic in two dimensions.

Claim Rejections – 35 USC §102

Claims 22-33, 38-45, 47-49, 51-53, 61-65, 74-77, 80-81, 84 and 87 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,158,574 to Stone (hereinafter referred to as "Stone"). Claims 22-30, 37-48, 51-65, 74-84 and 87 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. US2002/0127270 to Li (hereinafter referred to as "Li"). Applicants respectfully traverse these rejections.

Each of these rejections comes down to the position of the Office that the claimed implant and that of Stone and Li are produced in the same manner and contain the same components, and that therefore all of the physical limitations are met. The Action cites In re Best for the rule that

> "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. Thus, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable."

Applicants respectfully submit that neither Stone nor Li discloses or suggests the claimed invention.

Stone discloses a biocompatible and bioresorbable structure for implantation into the knee joint which assumes the form and role of a meniscus. This prosthetic meniscus promotes and provides a scaffold for the regeneration of tissue. The prosthetic meniscus of Stone is a dry, porous matrix of biocompatible bioresorbable fibers, a portion of which may be crosslinked. In some forms of the Stone invention, the fibers may be randomly oriented throughout the matrix. Alternatively, the fibers may be substantially circumferentially extending or substantially radially extending throughout the prosthetic meniscus. The matrix may also include glycosaminoglycans (GAGs) interspersed with the fibers.

The Stone method for fabricating a prosthetic meniscus includes placing a plurality of fibers and/or fibers and GAGs into a mold having a shape useful for knee joint function, subjecting the fibers (and GAGs) in the mold to two cycles of freezing and thawing, contacting the fibers or fibers and GAGs with a chemical crosslinking agent such that the fibers then assume the shape of the mold, and lyophilizing the resulting structure to obtain a dry, porous, volume matrix.

Li discloses a sheet membrane containing at least one layer of oriented biopolymeric fibers, such as collagen fibers. The sheet membrane is generally flat, but can be somewhat curved. When the sheet membrane contains two or more layers, the layers are secured to each other by fibrin glue, and preferably where the fibers in different layers are oriented in different directions.

The Li method includes reconstituting biopolymeric fibers dispersed in a solution, placing the reconstituted biopolymeric fibers around a mandrel, rotating the mandrel to convert the reconstituted biopolymeric fibers on the mandrel into a tubular membrane of oriented biopolymeric fibers, cutting the tubular membrane longitudinally after it has been dried on the mandrel, rolling the cut membrane into a tubular form that is an inversion of the tubular membrane, inserting the rolled membrane into a tubular mesh, and crosslinking the biopolymeric fibers to form a sheet membrane or oriented biopolymeric fibers.

The attached Declaration of co-inventor Timothy Ringeisen points out key processing differences between Stone and that of the present invention, and between Li and that of the present invention. Stone features a rotating piston or mold; Li features a rotating mandrel. Both references state that it is this rotation that gives rise to fiber alignment in Stone and Li (see, for example, col. 4, lines 27-30 in Stone, and Paragraph [0050] in Li). Ringeisen states that the present process does not feature such rotation, only compression. In view of these significant differences, it cannot be said that the respective products, i.e., that of the instant invention versus those of Stone and Li, are inherently the same.

The rotations in Stone and Li gives rise to their fiber orientation. At least in the Li document, the fibers are even aligned before the compression step! In Stone's application, Ringeisen states that the alignment of the fibers caused by the rotation of the piston would disrupt any formation of layers and plates. Regarding Li, Ringeisen states that rotation of the mandrel likewise would disrupt any formation of layers and plates. In contrast, in the present invention, the fibers become aligned by migrating through the fluid as a result of compression, and the movement of fluid out of the mold, leaving the fibers behind arranged into layers and plates. Thus, the mechanism by which fibers become oriented in Stone and Li is fundamentally different from the way in which they become oriented in the instant invention. Ringeisen states even further that the fiber orientation of Stone and Li is fundamentally different from that of the claimed invention.

Thus, the claimed invention is patentably distinguishable over the products of Stone and Li. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Claim Rejections – 35 USC §103

Claims 22-33, 36-65 and 74-87 were rejected under 35 U.S.C. §103(a) as being unpatentable over Stone in view of Li and further in view of U.S. Patent No. 6,428,576 B1 to Haldimann. Applicants respectfully traverse this rejection.

The Action applied Haldimann primarily to show that the use of plasticizers and particulates in implantable bio-polymers was well known to the skilled artisan at the time of the invention. Applicants have shown that neither Stone nor Li discloses or suggests the claimed invention. Applicants respectfully submit that Haldimann fails to remedy the deficiencies in Stone and in Li. Specifically, Haldimann likewise fails to disclose or suggest the invention of independent claim 22 featuring aligned fibers in the form of layers and/or plates, with fissures or fluid planes between the layers or plates of aligned fibers, and with this architecture occurring substantially throughout the structure, and which features are not disclosed or suggested by Stone or by Li. Similarly, Haldimann fails to disclose or suggest the invention of independent claim 31 directed to an implantable device featuring aligned polymer fibers, and where the polymer fibers on the periphery of the device are cross-linked, but those located away from the periphery are not cross-linked, and which features are not disclosed or suggests by either Stone or by Li. Likewise, Haldimann fails to disclose or suggest the invention of independent claim 39 directed to an implantable device featuring fibrous plates in a layered structure, with

the layering occurring on both the microscopic as well as the macroscopic level, the fibrous plates being formed by the application of compression to a mixture of fibers and fluid, which causes the alignment of fibers into the plate formation, and which features are neither disclosed or suggested by either Stone or by Li. Moreover, Haldimann fails to disclose or suggest the invention of independent claim 42 directed to a compressed fibrous matrix featuring multiple plates of oriented fibers, the plates being present throughout the device and being locked in a compact anisotropic structure.

Accordingly, this rejection should be withdrawn.

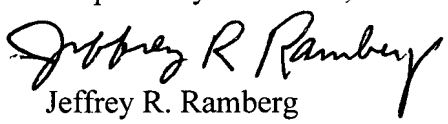
CONCLUSION

The processes of Stone and Li each feature a rotating component that helps align fibers, and this is a feature that is not shared by the instant patent application. Thus, it cannot be said that the Stone and Li processes are inherently the same as that of the present invention, thus, it does not automatically follow that the resulting products are the same. In fact, Ringeisen assures us that they are fundamentally different from one another.

In view of the amendments and the above remarks, Applicants respectfully submit that the instant application is in condition for allowance. Accordingly, Applicants respectfully request issuance of a Notice of Allowance directed to claims **22-26, 28-33, 36-50, 52-65 and 74-87**.

Should the Examiner deem that any further action on the part of Applicants would be desirable, the Examiner is invited to telephone Applicants' undersigned representative.

Respectfully submitted,



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April 23, 2007

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